

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of results and complications of percutaneous nephrostomy and hemodialysis for hemostasis in patients suffering from obstructive uropathy

Protocol summary

Study aim

Comparison of results and complications of percutaneous nephrostomy and hemodialysis for hemostasis in patients suffering from obstructive uropathy

Design

30 patients with supra vesical obstructive uropathy referred to Imam Khomeini s ER, after being informed about the study conditions and signing the consent were included in intervention 2-3 phase study. patients were divided to 2 groups randomly by using 4 block randomization . Group A: Patients will under go unilateral or bilateral per-cutaneous nephrostomy , urine output in the first hour and then every 6 hours post-operative will be checked to reach the optimum level suitable for elective surgery. Group B: A hemodialysis catheter will be inserted for these patients and the patients undergo internal medicine hemodialysis protocol and the BUN, Cr, Na, K level will be checked every 6 hours. The hemodialysis may be repeated before surgery in order to balance the electrolytes for surgery the complications of both groups such as failure of hemodialysis, failure of percutaneous nephrostomy and other unpredictable complication will be recorded. T1: The time between admission and reaching optimal electrolyte level surgery. Then the patients will undergo the major surgery such as ureteroscopy , jj insertion or resolving the obstruction. The electrolyte changes will be recorded until discharge. T2: The time between major surgery and discharge. T3: Duration of admission. T1 , T2 , T3 , pain level and the satisfaction level of the patients and complications of surgery will be compared in both groups.

Settings and conduct

This study will be conducted in the Imam Khomeini hospital. Because of the therapeutic procedures, blinding was not possible for the patients and physician. Outcome evaluators were not aware of the randomization protocols.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with obstructive uropathy who could not be operated urgently because of electrolyte disturbance. Exclusion criteria: Coagulopathy, active cutaneous infection of the flank and severe cardiovascular disorder

Intervention groups

Group A: Patients will under go unilateral or bilateral percutaneous nephrostomy. Group B: A hemodialysis catheter will be inserted for these patients and the patients undergo internal medicine hemodialysis protocol.

Main outcome variables

The time between admission and reaching optimal electrolyte level for surgery! The time between major surgery and discharge! Failure of hemodialysis! Failure of percutaneous nephrostomy! Duration of admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150509022168N5**

Registration date: **2018-01-15, 1396/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-15, 1396/10/25**

Update count: **0**

Registration date

2018-01-15, 1396/10/25

Registrant information

Name

Dinyar Khazaeli

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone	groups.
+98 61 3221 0695	Placebo
Email address	Not used
khazaeli-d@ajums.ac.ir	Assignment
Recruitment status	Parallel
Recruitment complete	Other design features
Funding source	
Expected recruitment start date	Secondary Ids
2017-12-11, 1396/09/20	empty
Expected recruitment end date	Ethics committees
2018-02-19, 1396/11/30	
Actual recruitment start date	1
empty	Ethics committee
Actual recruitment end date	Name of ethics committee
empty	Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Trial completion date	Street address
empty	Golestan blv, Ahvaz Jundishapur University of Medical Sciences
Scientific title	City
Comparison of results and complications of percutaneous nephrostomy and hemodialysis for hemostasis in patients suffering from obstructive uropathy	Ahwaz
Public title	Province
Comparison of percutaneous nephrostomy and hemodialysis for hemostasis in patients suffering from obstructive uropathy	Khouzestan
Purpose	Postal code
Treatment	15794-61357
Inclusion/Exclusion criteria	Approval date
Inclusion criteria:	2017-12-05, 1396/09/14
Patients with obstructive uropathy who could not be operated urgently because of electrolyte disturbance	Ethics committee reference number
Exclusion criteria:	IR.AJUMS.REC.1396.704
Coagulopathy Active cutaneous infection of the flank Severe cardiovascular disorder	Health conditions studied
Age	1
From 18 years old to 60 years old	Description of health condition studied
Gender	Obstructive uropathy
Both	ICD-10 code
Phase	N13
2-3	ICD-10 code description
Groups that have been masked	Obstructive and reflux uropathy
- Outcome assessor - Data analyser	Primary outcomes
Sample size	1
Target sample size: 30	Description
Randomization (investigator's opinion)	The time between admission and reaching optimal electrolyte level surgery
Randomized	Timepoint
Randomization description	From the referral of the patient until the proper condition of water and electrolyte for action
Patients were divided to 2 groups randomly by using permutation 4 block randomization. Randomization is done with random numbers.	Method of measurement
Blinding (investigator's opinion)	Hour
Single blinded	2
Blinding description	Description
Due to the types of therapies, blinding is not possible for the patient and physician. The outcome evaluator should not be aware of how people are treated in treatment	The time between major surgery and discharge
	Timepoint

From the patient's main surgery until discharge

Method of measurement

Hour

3

Description

Failure of hemodialysis

Timepoint

After surgery

Method of measurement

Based on patient records

4

Description

Failure of percutaneous nephrostomy

Timepoint

After surgery

Method of measurement

Based on patient records

5

Description

Duration of admission

Timepoint

From patient admission to discharge

Method of measurement

Hour

Secondary outcomes

1

Description

Blood urea nitrogen

Timepoint

At the first hour and then every 6hours post operative will be checked to reach the optimum level suitable for elective surgery.

Method of measurement

Laboratory test

2

Description

Blood creatinine

Timepoint

At the first hour and then every 6hours post operative will be checked to reach the optimum level suitable for elective surgery.

Method of measurement

Laboratory test

3

Description

Blood sodium

Timepoint

At the first hour and then every 6hours post operative will be checked to reach the optimum level suitable for elective surgery.

Method of measurement

Laboratory test

4

Description

Blood potassium

Timepoint

At the first hour and then every 6hours post operative will be checked to reach the optimum level suitable for elective surgery.

Method of measurement

Laboratory test

Intervention groups

1

Description

Intervention group: Patients will under go unilateral or bilateral percutaneous nephrostomy.

Category

Treatment - Surgery

2

Description

Intervention group: A hemodialysis catheter will be inserted for these Patients and the Patients undergo internal medicine hemodialysis protocol

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dinyar Khazaeli

Street address

Azadegan boulevard

City

Ahwaz

Province

Khouzestan

Postal code

1234587659

Phone

+98 61 3221 6104

Email

dinyar.khazaeli@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of

Ahvaz Jundishapur University of Medical

Full name of responsible person

Mohammad Badavi

Street address

Ahvaz, Golestan Blvd, Ahvaz Jundishapur University of Medical Sciences

City

Ahwaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 61 3373 8594

Email

info@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology of Ahvaz Jundishapur University of Medical

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dinyar Khazaeli

Position

Fellowship of robotic urologic surgeries and onco-urology

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Azadegan Blvd, Imam khomeni hospital

City

Ahvaz

Province

Khouzestan

Postal code

1234587659

Phone

+98 61 3221 6104

Email

khazaeli-d@ajums.ac.ir

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Fax

Email

dinyar.khazaeli@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available